

DETAILED ACTION

1. This is the initial Office action based on the 10/728074 application filed 12/04/2003. Claims 1-16, as originally filed, are currently pending and have been considered below.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- I. Claims 3-5 drawn to specific compositions of the container.
 - II. Claims 7, 10-11 & 15 drawn to the device comprising electrodes/transducer.
 - III. Claims 8-9 & 13-14 drawn to specific compositions of the element/compressible material
3. Claims 1, 2 & 12 link(s) inventions I through III. Claim 6 link(s) inventions II & III, but is distinct from I. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1, 2, 6 or 12. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I through III are directed to related devices. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different design and effect as each of container, electrodes/transducer & element/compressible material. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. By a telephone message left by Rose M. Thiessen on 12/21/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-5 & 12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-11 & 13-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

7. Claim 1 objected to because of the following informalities: it appears that the limitation "element" in line 4 should say "compressible element". Appropriate correction is required.

8. Claim 12 objected to because of the following informalities: it appears that the limitation "element" in lines 1, 2 & 4 should say "compressible element". Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 & 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Bombeck, IV (US 4981470).

Regarding claim 1, Bombeck discloses a device for determining a location of a visceral constriction in a body, a device comprising:

a catheter (intraesophageal catheter, 10) comprising a compressible element (balloon inflation pressure sensor, 16; col. 3 lines 27-29) having a volume dependent on compression of an element;

a volume detector for detecting a change in volume of a compressible element (col. 6 lines 36-43);

a position detector (col. 4, lines 38-39) for detecting a position of a compressible element with respect to a reference position measured along a length of a catheter (col. 4, lines 46-50).

Regarding claim 2, Bombeck discloses wherein the compressible element comprises a balloon filled with liquid or gas (col. 6 lines 35-36).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 3 & 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bombeck in view of both Wallace et al. (US 5009662) and Fiddian-Green (US 5456251).

Regarding claims 3 & 4, Bombeck discloses a device wherein an interior balloon is in fluid communication with an interior of the catheter (col. 6 lines 35-36);

a second tube (balloon inflation channel, 40) connecting the catheter to the measurement and read-out device (col. 5, lines 40-42);

a measurement and read-out device for detecting a volume change in the container by measuring a physical value related to the volume change, and displaying or recording the physical value (col. 6, lines 41-43);

Bombeck does not appear to explicitly disclose a device further comprising:

a container having a variable volume comprising a vessel equipped with a piston;
a first tube connecting the catheter to the container; and
a stopcock, wherein the stopcock can be placed in a first position or a second position, wherein when the stopcock is placed in the first position a connection between the balloon and the container is opened and a connection between the balloon and the measurement and read-out device is blocked, and wherein when the stopcock is placed in the second position a connection between the balloon and the measurement and read-out device is opened and a connection between the balloon and the container is blocked.

However, Wallace et al. teaches a device further comprising:

a container having a variable volume comprising a vessel equipped with a piston (inflation/deflation syringe, 27);

a first tube connecting the catheter to the container (housing, 31);

and

Fiddian-Green teaches a device further comprising:

a stopcock (three-way stopcock, 30), wherein the stopcock can be placed in a first position or a second position, wherein when the stopcock is placed in the first position a connection between the balloon and the container is opened and a connection between the balloon and the measurement and read-out device is blocked, and wherein when the stopcock is placed in the second position a connection between the balloon and the measurement and read-out device is opened and a connection between the balloon and the container is blocked. The Examiner notes that it is well

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known to one of ordinary skill in the art, stopcocks, when placed in different positions, block the flow of one opening and allow the flow through another opening.

Bombeck and Wallace et al. and Fiddian-Green are analogous art because they are from the same field of endeavor/problem solving area of catheters containing expandable balloons on the distal end for use in medical diagnosis and treatment. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Bombeck, Wallace et al. and Fiddian-Green before him or her to modify the catheter of Bombeck to include a container having a variable volume and a first tube connecting the catheter to the container of Wallace et al. and to include the stopcock of Fiddian-Green to change the flow between the first and second tubes when the stopcock is in a first or second position. Bombeck discloses that a device may be attached for inflating the balloon (col. 6, lines 35-36), providing the means of inflating the balloon with the use of a container having a variable volume comprising a vessel equipped with a piston, and connecting the container to the catheter using a first tube as taught by Wallace et al. is combining these prior art elements to yield the predictable result of inflating a balloon. Additionally, stopcocks are well known to one of ordinary skill in the art, the stopcock as disclosed by Fiddian-Green is capable of being placed in a first or second position to alter fluid flow through the first or second tubes. The motivation for doing so would have been "to provide a catheter that monitors ... air pressure" (col. 3, lines 4-6) as disclosed by Bombeck, to provide a "pressure monitoring system for medical procedures which facilitates the display of balloon pressure to the user" (col. 2, lines 63-65) as taught by Wallace et al. and to provide a balloon member

provide on an elongated tube member (Abstract, line 10) as taught by Fiddian-Green. Therefore, it would have been obvious to combine Bombeck with Wallace et al. and Fiddian-Green to obtain the invention in the instant claims 3 & 4.

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bombeck in view of Wallace et al. and Fiddian-Green as applied to claim 3 above, and further in view of Brown (US 2845930).

Bombeck, Wallace and Fiddian-Green teach the invention as discussed above.

Regarding claim 5, Bombeck does not appear to explicitly disclose a device wherein a container comprises a balloon.

However, Brown discloses a device wherein a container comprises a balloon (38).

Bombeck/Wallace et al./Fiddian-Green and Brown are analogous art because they are from the same field of endeavor/problem solving area of catheters for use in medical diagnosis and treatment. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Bombeck/Wallace et al./Fiddian-Green and Brown before him or her to modify the catheter of Bombeck to have a container having a variable volume (as taught above using Wallace et al) and to have modified the container to comprise a balloon as taught by Brown. The Examiner notes that using a container having a variable volume, and more specifically the container being a compressible balloon, is a technique for expelling a substance from the balloon and into a catheter well known to one of ordinary skill in the art. The Examiner notes that the substitution of a container having a variable volume being a

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vessel equipped with a piston as disclosed by Wallace with a balloon as taught by Brown is a simple substitution of one known element for another to obtain the predictable result of inflating a balloon that is in fluid communication with an interior of a catheter. Therefore, it would have been obvious to combine Bombeck/Wallace et al./Fiddian-Green with Brown to obtain the invention in the instant claim 5.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bombeck in view of Lane ().

Regarding claim 12, Bombeck discloses a device according to claim 1 and further wherein an element comprises a first end (distal end, 58) and a second end (area around exterior surface, 20 just below inflation pressure sensor, 16), an element comprising a balloon situated at a first end (balloon inflation pressure sensor, 16; col. 3 lines 27-29) and a rigid hollow body situated at a second end (intraesophageal catheter, 10), wherein a balloon and a rigid body are connected by a tube (through ports, 52), wherein a gas is contained within an element (col. 6 lines 35-36),

Bombeck does not appear to explicitly disclose a device wherein a rigid hollow body further comprises a compressible body which is separated from a gas by a membrane such that a compressible body is capable of being compressed by gas which is pressed out of a balloon and into the rigid hollow body and wherein a compressible body comprises a compressible material, wherein a compressible material is electrically conductive, and wherein an electrical resistance of a compressible material is dependent on a compression of a compressible material.

However, Lane et al. discloses disclose a device wherein a rigid hollow body further comprises a compressible body which is separated from a gas by a membrane such that a compressible body is capable of being compressed by gas which is pressed out of a balloon and into the rigid hollow body, and wherein a compressible body comprises a compressible material (Best seen in Fig. 14 wherein there are two balloon portions, inner balloon 860 and outer balloon 865), and wherein a compressible material is electrically conductive, and wherein an electrical resistance of a compressible material is dependent on a compression of a compressible material (§0087, lines 9-11).

Bombeck and Lane et al. are analogous art because they are from the same field of endeavor/problem solving area of catheters for use in medical diagnosis and treatment. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Bombeck and Lane et al. before him or her to modify the hollow rigid body of Bombeck to include a compressible body which is separated from a gas by a membrane such that a compressible body is capable of being compressed by gas which is pressed out of a balloon and into the rigid hollow body, and wherein a compressible body comprises a compressible material, and wherein a compressible material is electrically conductive. Lane et al. teaches two separate balloons, balloons being a compressible material, wherein the separate balloons are capable of gas pressed out of the balloon and into the rigid hollow body compresses the compressible body and wherein the compressible body is electrically conductive in combination with Bombeck et al. The motivation for doing so would have been “to provide a catheter that monitors ... air pressure” (col. 3, lines 4-6) as disclosed

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by Bombeck and to provide an inner and outer surface balloon, with which the inner surface balloon is electrically conductive (§ 10087) as taught by Lane et al. Therefore, it would have been obvious to combine Bombeck with Lane et al. to obtain the invention in the instant claim 12.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. O'Neill et al. (US 5324260), Zalesky et al. (US 2005/01315003).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on (571) 272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 4123

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